MISCELLANEOUS

Document AR on Form PTO-1449 submitted December 14, 2001 has not been considered by the Examiner. The Examiner states that a copy did not accompany the form. In reply, the Applicants note that a copy did, indeed, accompany the form, as indicated on the attached mailroom date-stamped receipt of the same date. For the Examiner's convenience, another copy is being submitted with this paper. Perhaps some confusion exists because the one-page document itself does not bear the title "Molecular Cloning", but instead bears the subheading "CONCENTRATING NUCLEIC ACIDS".

OBJECTIONS

The Examiner objected to the disclosure, citing a minor matter on page 2 of the Office Action. The supposed mislocation of lines 1-4 of page 12 is not addressed by amendment. These lines introduce the Brief Description of the Drawings, not the Description of the Preferred Embodiment.

REJECTION UNDER 35 USC §112, FIRST PARAGRAPH

Claims 20-32 were rejected under 35 USC §112, first paragraph, as set forth on pages 3-4 of the Office Action. The Examiner's comments will be addressed in turn.

In lines 7-10 of page 3, the Examiner states that the specification fails to disclose carrying out steps separate from each other as required in the last two lines of claims 20 and 25, and separate preparation of solutions as required in the last two lines of claim 27. In reply, the Applicants refer the Examiner to the specification at page 9, lines 19-28, for example. It is noted that the claims have been amended to mimic the language of the specification more closely. No change in scope is believed to have been made by these amendments to claims 20, 25 and 27.

In lines 11-14 of page 3, the Examiner states that the specification fails to disclose "destroying a nucleic acid-bearing material" as required in certain claims, asserting that the specification describes only releasing nucleic acids from a nucleic acid-bearing material. In reply, the Applicants submit that the claim language should be interpreted as calling for the destroying of the supporting relationship between the nucleic acid and the material bearing it. Nevertheless, to enhance the clarity of the claimed

expression, the claims have been amended in accordance with the Examiner's suggestion.

In lines 15-24 of page 3, the Examiner states that the specification fails to disclose a method as required by claim 26 for recovering nucleic acids from a nucleic acid-bearing material. In reply, the Applicants are confused as to the Examiner's apparent attempts to limit the invention to three pages of the 45 page disclosure. Further, the step of providing a first solution through the step of eluting the nucleic acid are closely similar to the basic steps of non-rejected claims, such as claim 20, and the step of removing alcohol and salt is supported in the specification on pages 37-38, for example.

On page 4, lines 1-11, the Examiner states that the specification fails to describe isolating an adsorbing solid phase to which nucleic acids are bound as required by claims 27-32. In reply, the Applicants note that the steps recited in these claims are fully supported in the specification, and the end result of the steps recited is to isolate an adsorbing solid phase (amended, a substance containing silicon oxide) to which a nucleic acid is bound. Concerning claim 27, the claim is not restricted to a method for only preparing first, second, and third solutions as

implied by the Examiner (note the open-ended "comprises the steps of" language). Claim 32, similarly, is not limited by only providing a first solution and then carrying out two steps of transferring.

REJECTION UNDER 35 USC §112, SECOND PARAGRAPH

Claims 20-32 were rejected under 35 USC §112, second paragraph, as set forth on pages 4-6 of the Office Action. The claims have been amended to enhance their clarity without narrowing their scope in the context of amendments to address these rejections. In certain cases, the Examiner's helpful suggestions have been adopted. However, certain of the rejections should be addressed because the Examiner's position appears to be unsupported completely by the statute or by relevant case law.

In particular, the Examiner's objection to reciting "a step" followed by describing the function of the step is well-settled to be an appropriate way to express an invention. Nevertheless, the claims have been amended in accordance with the Examiner's suggestion.

Concerning the meaning and scope of conducting steps separately, the Applicants refer the Examiner to the specification at page 9, lines 19-28, for example, which

describe the conduction of certain steps "separately and in turn". The separate conduction of these steps provides certain advantages over the prior art with regard to establishing optimum conditions for the binding of the released nucleic acid to the substance containing silicon oxide. It is noted, furthermore, that the primary reference to Boom et al, US 5,234,809 (applied in the rejection discussed below), discloses a process for isolating a nucleic acid in which it is required that the steps performed separately according to the present invention be performed simultaneously.

The Applicants do not understand the Examiner's suggestion to cancel claims 26-32, which provide additional scope of protection for the invention set forth in the specification.

REJECTION UNDER 35 USC §103(a)

Claims 20-32 were rejected under 35 USC §103(a) as being unpatentable over Boom et al, US 5,234,809 (Boom), in view of Seligson et al, US 4,935,342 (Seligson). The Applicants traverse as follows.

According to the present invention, the steps of (1) releasing the nucleic acid from the nucleic acid-bearing

material, (2) adding the chaotropic agent to the solution, and (3) adding the solution containing the released nucleic acid and the chaotropic agent to a substance containing silicon oxide are clearly separated. By separating these three steps, the releasing and binding are executed suitably to improve recovery of the nucleic acid. More specifically, the Applicants have found optimum conditions for the separate releasing and binding steps to enhance the recovery of the nucleic acid.

Boom, on the other hand, requires that the chaotropic substance, silica particles, and nucleic acid be mixed at the same time to execute the lysis and bind procedures almost instantaneously. See, for example, column 4, lines 9-15 and 60-66. According to Boom, the lysis and bind procedures cannot be executed at optimum conditions, so that the ultimate recovery of nucleic acids is unnecessarily low.

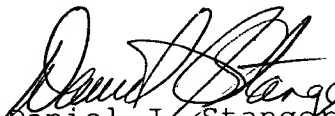
Furthermore, Seligson does not relate to the nucleic recovery method using a chaotropic substance and solid phase including silica. Instead, Seligson's principle of adhering a nucleic acid to a solid phase is quite different from that of Boom and that of the present invention. Seligson fails to show the concept of contacting and mixing the solid phase having a predetermined weight into the solution. Therefore,

the Applicants submit that the person of ordinary skill would not combine the teachings of Boom and Seligson as asserted by the Examiner, and would not reach the present invention by any such combination.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants request reconsideration of the rejection and allowance of the claims.

Respectfully submitted,



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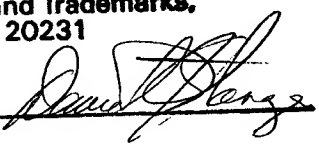
on 1/8/03 by 

MARKED-UP VERSION OF REWRITTEN CLAIM(S)

20. (Amended) A method for recovering a nucleic acid[s] from a nucleic acid-bearing material, which comprises the steps of:

[a step for destroying] releasing a nucleic acid from a nucleic acid-bearing material [to release the nucleic acids therefrom in] and forming an aqueous solution containing the released nucleic acid;

[a step for] adding a [binding accelerator] chaotropic agent to an aqueous solution containing the released nucleic acid[s, after the destroying step];

[a step for containing] contacting and mixing the solution containing the released nucleic acids and the [accelerator] chaotropic agent with [an adsorbing solid phase] a substance containing silicon oxide thereby to bind the nucleic acids to the substance [adsorbing solid phase, after the adding step];

[a step for] isolating the [adsorbing solid phase] substance to which the nucleic acid[s are adsorbed] is contacted from the solution[, after the contacting step];

[a step for] washing the isolated [adsorbing solid phase] substance with an aqueous washing solution containing alcohol[, after the isolating step]; and

[a step for] eluting the nucleic acid[s] bound to the [adsorbing solid phase] substance from the adsorbing solid phase[, after the washing step],

wherein the [destroying] releasing step through the eluting step are [separately] conducted [from each other] separately and in turn.

25. (Amended) A method for recovering a nucleic acid[s] from a nucleic acid-bearing material, which comprises the steps of:

[a step for destroying] releasing a nucleic acid from a nucleic acid-bearing material [to release the nucleic acids therefrom in] and forming an aqueous solution containing the released nucleic acid;

[a step for] adding a [binding accelerator] chaotropic agent to an aqueous solution containing the released nucleic acid[s, after the destroying step];

[a step for containing] contacting and mixing the solution containing the released nucleic acid[s] and the [accelerator] chaotropic agent with [an adsorbing solid phase]

a substance containing silicon oxide thereby to bind the nucleic acids to the substance [adsorbing solid phase, after the adding step];

[a step for] isolating the [adsorbing solid phase] substance to which the nucleic acid[s are] is adsorbed from the solution[, after the containing step];

[a step for] washing the isolated [adsorbing solid phase] substance with an aqueous washing solution containing alcohol and acetate; and

[a step for] eluting the nucleic acid[s] bound to the [adsorbing solid phase] substance, thereby to obtain a purified nucleic acid[s],

wherein the [destroying] releasing step through the eluting step are [separately] conducted [from each other] separately and in turn.

26. (Amended) A method for recovering a nucleic acid[s] from a nucleic acid-bearing material, which comprises the steps of:

providing a first solution for releasing a nucleic acid from [destroying] a nucleic acid-bearing material [to release the nucleic acids therefrom];

providing a second solution by adding a [binding accelerator] chaotropic agent to an aqueous solution containing the released nucleic acid[s];

providing a third solution containing the [accelerator] chaotropic agent for binding the released nucleic acid[s] to [an adsorbing solid phase] a substance containing silicon oxide;

[separating] isolating the [adsorbing material] substance to which the nucleic acid[s are adsorbed] is bound from the solution;

providing an aqueous solution containing alcohol and a salt for washing the isolated [adsorbing phase] substance;

eluting the nucleic acid[s] bound to the substance [adsorbing solid phase]; and,

removing alcohol and salt contained in the eluted nucleic acid[s], thereby to obtain a purified nucleic acid[s];

wherein the first solution, the second solution and the third solution are provided separately and in turn.

27. (Amended) A method for isolating [an adsorbing solid phase] a substance containing silicon oxide to which a nucleic acid[s are bonded] is bound, which comprises the steps of:

providing a first solution for releasing a nucleic acid from [destroying] a nucleic acid-bearing material [to release the nucleic acids therefrom];

providing a second solution by adding a [binding accelerator] chaotropic agent to an aqueous solution containing the released nucleic acid[s, after the destroying step]; and

providing a third solution containing the [accelerator] chaotropic agent for binding the released nucleic acid[s] to [an adsorbing solid phase] a substance containing silicon oxide[, after the step of providing a second solution],

wherein the first solution, the second solution and the third solution are [prepared] provided separately and in turn.

28. (Amended) The method according to claim 27, which further comprises the step of separating the [adsorbing solid phase] substance from the third solution, conducted separately after the binding step.

29. (Amended) The method according to claim 28, which further comprises the step of providing an aqueous fourth [aqueous] solution containing a salt and an alcohol for

washing the separated [adsorbing solid phase] substance, conducted separately after the separating step.

30. (Amended) The method according to claim 29, which further comprises the step of providing an aqueous fifth [aqueous] solution containing a buffer for eluting the nucleic acid[s] from the [solid phase] substance.

31. (Amended) The method according to claim 30, which further comprises the step of removing alcohol and salt remaining in the eluted nucleic acid[s].

32. (Amended) A method for isolating [an adsorbing solid phase] a substance containing silicon oxide to which a nucleic acid[s are bonded] is bound, which comprises the steps of:

providing a first solution for releasing a nucleic acid from [destroying] a nucleic acid-bearing material [to release the nucleic acids therefrom];

transferring an aqueous solution containing the released nucleic acid[s] to a second solution containing a [binding accelerator] chaotropic agent[, after the destroying step]; and

transferring the aqueous solution containing the released nucleic acid[s] to a third solution containing the [accelerator] chaotropic agent for binding the nucleic acid[s] to [an adsorbing solid phase] a substance containing silicon oxide, [after the step of transferring the aqueous solution to the second solution]

wherein the steps of providing the first solution, transferring the aqueous solution to the second solution, and transferring the aqueous solution to the third solution, are conducted separately and in turn.